REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

Claims 24-27, 29-31 and 35-44 are pending in the application. Claims 24-27, 29-31 and 35-44 have been rejected.

Claim 35 has been amended herein. Applicants respectfully assert that the amendments to claim 35 add no new matter.

CLAIM REJECTIONS

35 U.S.C. § 103 Rejections

In the Office Action, the Examiner rejected claims 24-39 and 42-44 under 35 U.S.C. § 103(a), as being unpatentable over Luiken (US 2001/0055566) in view of Alfano et al (US 6,240,312). According to the Examiner:

> Luiken discloses tumor screening related methods including administration of fluorescent dye and irradiation with visible and fluorescent (excitation) radiation to produce images stored on an image sensor (0004-0007) for the purpose of diagnosing cancerous tissues. The light excitations including both monochromatic light, polychromatic light, and combinations of flashing sequences (0009, 0018-0024), [sic] The acquisition of real images and fluoroscopic images during different time periods (0018-0028, 0030), washing of excess dye before image-capturing (0029), and administrations of antibodies associated with GI cancer including CEA (0034-0038). Luiken does not disclose the use of an ingestible imaging capsule, rather [sic] focuses on methods involving endoscopes of certain capabilities and other techniques rather than the specific properties of the endoscopes or other imagers used. Attention is then directed to the secondary reference by Alfano et al which

discloses and [sic] ingestible internal device for wireless capturing and imaging of the GI tract (Col 2 Line 10-65) to enable cancer diagnosis and treatment (Col 3 Line 65-Col 4 Line 59. It would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized the methods of wireless transmission and endoscopy of Alfano et al with those method of Luiken for the staining and diagnostic imaging of tissues to enable portable diagnosis of cancer and other diseases with micro-scale technology and onboard storage/transmission.

I. Luiken (US 2001/0055566)

Applicants respectfully traverse the Examiner's reading of Luiken. Luiken discloses a method for direct viewing of tissue for detection of diseased tissue. Luiken discloses a technique in which in vivo body parts are irradiated with light having at least one excitation wavelength in the range from about 400 nm to about 500 nm. **See paragraph [0018] (emphasis added).** Fluorescence emanating from a fluorescent targeting construct administered to the subject and which has specifically bound to and/or been taken up by the diseased tissue in the body part, in response to the at least one excitation wavelength is directly viewed to determine the location and/or surface area of the diseased tissue in the subject. **See paragraph [0018] (emphasis added).** ...[T]he excitation light used in practice of the invention diagnostic methods will contain at least one wavelength of light that illuminates surrounding tissue as well as excites fluorescence from the fluorescent targeting construct used in practice of the invention methods. .....To compensate for the tendency of such background effect to obscure the desired diagnostic image, it is preferred to use a filter to screen out wavelengths above about 500 nm in the excitation light, thereby eliminating wavelengths that would be reflected from healthy tissue so as to cause loss of resolution of the fluorescent image. Alternatively, it is possible to view the diagnostic site through a filter that substantially screens out wavelengths other than the peak emission wavelength of the fluorophore used..... Use of a filter in the practice of the invention diagnostic methods is expressly intended to be encompassed by the term "directly viewing" as applied to the invention diagnostic methods. **See paragraph [0019] (emphasis added).**

The excitation light may be directed by any convenient means into a body cavity or surgical opening containing a targeting construct administered as described herein and the fluorescent image so produced can be directly visualized by the eye of the observer without aid from an endoscope. With or without aid from any type of endoscopic device, the fluorescent image produced by the invention method is such that it can be viewed without aid of an image processing device, such as a CCD camera, TV monitor, photon collecting device, and the like. **See paragraph [0023] (emphasis added).**

Further, in the Background section of Luiken, it is disclosed that U.S. Patent No. 4,768,513 discloses a procedure in which a dye is applied to a body part suspected of containing a tumor usually by local injection. The dye is allowed to concentrate in tumors and clear from healthy tissue over a period of days, and then the body part is irradiated with alternate pulses of two light sources: a white light of a known intensity and a fluorescence-exciting laser light. **See paragraph [0009] (emphasis added).** This is not the same as the flashing mode (recited in independent claim 25 of Applicants' claimed invention) that provides a light period and a dark period.

It is thus clear from the above description, which is taken directly from Luiken, that this reference discloses a method which does not perform the steps of (1) **flashing illumination within the GI tract, thereby providing a light period and a dark period;** and

(2) **obtaining a fluorescent image of the GI tract tissue during the dark period on an image sensor within said ingestible imaging capsule** as recited in independent claim 24.

There is no flashing step disclosed in Luiken. There is no flashing mode in Luiken. There is no step of obtaining a fluorescent image on an image during the dark period on an image sensor disclosed in Luiken. There is no dark period disclosed in Luiken. Luiken discloses a technique in which the image is directly viewed through the use of an endoscope. To help one to view the image, part of the light is filtered. No device is disclosed in Luiken (other than an endoscope) that is used to capture or view the image. In fact, Luiken teaches away from Applicants' claimed invention---which

uses an image sensor to obtain a fluorescent image----because Luiken specifically states in paragraph [0023] that the image can be viewed without the aid of an image processing device such as a CCD camera, TV monitor, photon collecting device, and the like. Finally, the discussion in the background section of Luiken does not disclose flashing as recited in Applicants' claimed invention and described in Applicants' specification. In particular, the discussion in paragraph [0009] of Luiken refers to a body part being irradiated with alternate pulses of two light sources: a white light and a fluorescence exciting laser light. This is not a flashing mode comprising of a light period and a dark period. Here, the system is one in which two light sources alternately irradiate an object or body tissue.

With respect to amended independent claim 35, it can be clearly seen that Luiken does not perform the steps of: (1) **activating illumination of the in-vivo imaging capsule in a flashing mode having alternating light and dark periods**; and (2) **capturing light remitted during the flashing mode from said cells onto a light detector within the in-vivo imaging capsule**. There is no flashing mode as recited in the independent amended claim 35 of Applicants' claimed invention and there is no step of capturing remitted light onto a light detector. As explained above, Luiken teaches away from capturing images using light detectors or any type of similar devices.

II. Alfano (U.S. Pat. No. 6,240,312)

Alfano discloses a wireless, remote-controllable, micro-scale device adapted for use inside a patient's body. The device is an in vivo imaging device for which various embodiments of mobility are discloses. For example, a first implementation discloses a propeller for the motion mechanism; the second embodiment discloses a micro tractor treads; the third embodiment discloses a suction-type conveyor belt; the fourth embodiment discloses a propeller and a gas jet. Throughout the specification, the device is described as having a light source comprising LED's (light emitting diodes), lasers or photographic flash lamps; see for example, col. 6, lines 25-27; lines 47-49. However, it is clear that the "flash lamps" to which the specification refers are embodiments of a particular type of light source

and in no way imply the use of a flashing mode providing a light period and a dark period. No such light and dark periods are mentioned, suggested or even remotely implied in Alfano.

Therefore, with respect to independent claim 25 and amended independent claim 35, Alfano certainly does not disclose the steps of: **flashing illumination within the GI tract, thereby providing a light period and a dark period**; and

obtaining a fluorescent image of the GI tract tissue during the dark period on an image sensor within said ingestible imaging capsule; as recited in claim 25 or the steps of **activating illumination of the in-vivo imaging capsule in a flashing mode having alternating light and dark periods**; and **capturing light remitted during the flashing mode from said cells onto a light detector within the in-vivo imaging capsule** as recited in amended independent claim 35.

III. Conclusion

As has been shown above, neither Luiken nor Alfano discloses all of the steps of independent claims 25 and amended independent claim 35. The combination of these two references does not result in an application that discloses all of the elements of either independent claim 25 or independent amended claim 35 of Applicants' claimed invention. Luiken was shown to be deficient in two of the steps of the mentioned independent claims and Alfano, certainly did not cure these deficiencies. Similarly, the additional reference of Akashi (novel Gastric Cancer Associated Mucin Antigen Defined by A3D4) does not at all cure the deficiencies of Luiken or Alfano. Any combination of these three references does not disclose all of the steps recited in independent claim 25 or independent amended claim 35.

Therefore, in view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the

prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

No fees are believed due in connection with this paper. However, if any such fees are due, please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

Claude R. Narcisse

Claude R. Narcisse
Attorney/Agent for Applicant(s)
Registration No. 38,979

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Pearl Cohen Zedek Latzer, LLP
1500 Broadway, 12th Floor
New York, New York 10036
Tel: (646) 878-0800
Fax: (646) 878-0801